

REMARKS

Applicants respectfully request entry of this amendment. Claims 34-56 will remain pending following entry of the amendment. The amendment of claims 34, 35, 38, 39, 42, 43, 48-50, 52-55 is supported by the claims and specification as originally filed, and no new matter is introduced by this amendment.

Claim Rejections under 35 U.S.C. § 112, 12

Claims 35, 37-39, 42-46 and 48-56 stand rejected as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 35, 52-54 have been amended to clarify the number of shock waves are within the limitations of the claim from which each of these claims depends. Claims 35, 38, 39, 42-43 have been amended to no longer depend on a cancelled claim. Claims 48-50 have been amended to refer to claim 47, removing the dependencies of claims 48-56 on claims 34, 38 and 46.

Claim Rejections under 35 U.S.C. § 103(a)

Claims 34-37, 39-48 and 50-56 stand rejected as allegedly rendered obvious by U.S. Patent No. 6,334,069 to George et al. ("George") in view of U.S. Patent No. 6,390,995 to Ogden et al. ("Ogden") in view of "Effects of Shock Waves on Microcirculation in Critical Limb Ischemia" by Sanctis et al. ("Sanctis"). Applicants respectfully request reconsideration and withdrawal of the rejection as a person having ordinary skill in the art of shock wave treatment is not provided obviousness guidance to (i) substitute George's teachings of electromagnetic wave treatment (i.e. radio frequency waves) of skin grafts with Ogden's and Sanctis' high energy shock wave treatment (i.e. acoustic pressure waves) without suggestion of any similar operation or effects on the body between these different technologies and (ii) the long-established and relevant prior art of record EP 0 324 711 A2 to Chvapil et al. ("Chvapil") instructs that very low doses of 10 shock waves are required for healing split thickness wounds

and that healing is not observed and inhibited at the higher shock wave dosages discovered by Applicants' invention and therefore specifically discourages substituting Ogden's and Sanctis' high dose shock wave treatments used in other soft tissue treatments (not skin grafts or flaps) for George's electromagnetic treatment of skin grafts.

The Office Action argues that George discloses "a method and apparatus for the treatment of chronic wounds in a patient's skin using pulsed electromagnetic energy," but fails to "specifically teach to treat skin using shock wave pulses provided by a shock wave applicator having the claimed number of pulses and energy flux density." The Office Action cites Ogden as curing such deficiencies of George's failure to teach shock wave treatment of skin flaps and skin grafts in view of Ogden disclosing a range of between 500-10,000 shock waves to treat bone and musculoskeletal environments. The Office Action further cites Sanctis as teaching a shock wave applicator having pulses with an energy flux density of 0.03mJ/mm^2 to $.5\text{mJ/mm}^2$.

The Office Action concludes that based on the cited references, "it would have been obvious for one skilled in the art to replace one type of wave (EM waves) for another (shock waves) to treat skin in order to provide tissue angiogenesis in the grafted area" and that the "the substitution of one known wave for another would have yielded predictable results to one skilled in the art at the time of the invention." Applicants respectfully request reconsideration of such conclusion in view of the further unconsidered and clear differences between the technologies of the cited prior art and the Chvapil prior art disclosure discouraging high shock wave dosages taught by Ogden for treating skin flaps and grafts.

Under 35 U.S.C. § 103, the Patent Office bears the burden of establishing a prima facie case of obviousness. *In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988). There are four separate factual inquiries to consider in making an obviousness determination: (1) the scope and content of the prior art; (2) the level of ordinary skill in the field of the invention; (3) the differences between the claimed invention and the prior art; and (4) the existence of any objective evidence, or "secondary considerations," of

non-obviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966); *see also KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007). An “expansive and flexible approach” should be applied when determining obviousness based on a combination of prior art references. *KSR*, 127 S. Ct. at 1739. However, a claimed invention combining multiple known elements is not rendered obvious simply because each element was known independently in the prior art. *Id.* at 1741. Rather, there must still be some “reason that would have prompted” a person of ordinary skill in the art to combine the elements in the specific way that he or she did. *Id.*; *In re Icon Health & Fitness, Inc.*, 496 F.3d 1374, 1380 (Fed. Cir. 2007). Also, modification of a prior art reference may be obvious only if there exists a reason that would have prompted a person of ordinary skill to make the change. *KSR*, 127 S. Ct. at 1740-41.

The Office Action's rationale for substituting George's EM waves with Ogden's and Sanctis' shock waves because they are broadly waves capable of medical treatment fails to consider that these respective waves are unrelated in form and effect on the body are not predictably interchangeable given different wave characteristics (e.g. ultrasound, lasers, radiation, light, shock waves and EM waves are all well-known as providing different possible effects to body tissues). Specifically, George discloses that:

the present method, which utilizes **electromagnetic energy** . . . The term **electromagnetic energy includes effects from its magnetic energy and/or electrical energy components.**

See col. 9, Ins. 32-37. George states that treatment energy waves are “primarily defined as Radio Waves frequencies,” *see* col. 9, l. 44, and reiterates application of “RF energy” in the disclosed treatment. *See* cols. 12-18; FIGS. 9 and 10 (RF pulse applicators).

By contrast, as set forth in the Applicants' specification, the claimed invention is directed to applying shock waves which convert electrical energy into mechanical “pressure waves” in a “fluid medium” that are propagated into the body. *See* Applicant's published application at [0002]. At col. 2, Ins. 1-25, the cited Ogden reference explains

how shock waves are distinguished from other waves, particularly ultrasound, by a very steep pressure spike and gradual relaxation with virtually no oscillation to permit passage through soft tissue. Sanctis at p. S72 similarly describes that shock waves provide focal pressure (measured by MPa) delivered from a lithotripter, not application of electromagnetic fields. Where shock wave treatment of Ogden and Sanctis employ neither the magnetic energy nor electrical energy component to as required by George's EM waves delivering very different RF pulses, no disclosure in the cited art provides any predictable and enabling disclosure as to how or why one of ordinary skill in the art unfamiliar with Applicants' discovery would decide to replace George's EM waves and RF application to skin flap and graft healing with direct stress pressure wave treatments having very different wave characteristics and resulting effects on body tissues.

In this regard, and unconsidered in the pending Office Action arguments, Applicants also specifically disclose at [0005] of their published specification highly relevant prior art of shock waves taught to only applied at very low dosages to have an effect on split thickness skin wounds: "Studies in pig skin defects found that low energy shock waves stimulate skin healing whereas high-energy shock waves slowed healing (Haupt and Chvapil, 1990). In contrast to the study of Haupt and Chvapil, where a low number of impulses was applied, the present invention surprisingly revealed that the application of at least 200, preferably at least 350, most preferably at least 500 impulses allows a successful treatment of soft tissue orders." The Haupt and Chvapil study, reflected in EP 0 324 711 A2 (Chvapil) that was made of record in Applicants' information disclosure statement (IDS) filed August 2, 2006, teaches at pp. 6-9 (Example 1) that pigs' split thickness wounds showed enhanced healing only with application of ten shock waves at the lowest 14 kV shock wave generator setting. Chvapil specifically instructs that intermediate energies ranging from 100 shock waves at 14 kV and 10 shock waves at 18 kV "were ineffective" (see p.9) and "[w]ith increased numbers of SW (500 SW and 100 SW at 14 kV, 100 SW at 18 kV) healing was significantly inhibited." (emphasis added).

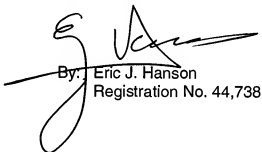
MPEP 2141.02(VI) requires that the prior art must be considered in its entirety, including disclosures that teach away from the claimed invention. Based on Chvapil's long-standing teachings against treating a split thickness wound (like skin grafts/flaps) with more than 10 shock waves only at a low shock wave generator setting, persons having ordinary skill in the relevant art of shock wave treatment are explicitly guided away from, not predictably toward, combining Ogden's application of high dosage shock waves (500 to 10,000 SW) to other soft tissues as a substitute for George's EM waves' skin graft treatment that applies RF pulses and not high energy pressure waves. Particularly where neither Ogden or Sanctis' soft tissue treatments suggest any treatment of skin flaps and grafts similar to Chvapil's split thickness wound study, none of these cited references indicates any suggestion to apply those higher dosage treatments of other body tissue environments specifically to skin flaps and grafts against the long-standing teachings of Chvapil that instructs not to apply such high wave dosages to such specific flap and graft tissues. As the most relevant shock wave teachings related to skin grafts/flaps (Chvapil's split thickness study) in the collective prior art discourages the claimed invention's treatment of skin grafts/flaps with from 200 to 5000 shock waves at an energy flux density of from 0.05 mJ/mm^2 to 0.3 mJ^2 (independent claim 34 and dependent claims 35-46) and with from 350 to 5000 shock waves at an energy flux density of from 0.05 mJ/mm^2 to 0.3 mJ/mm^2 to a wound area of one of a skin flap and skin graft of at least 5 cm^2 (independent claim 47 and dependent claims 48-56), Applicants invention for treating skin flap and grafts with high doses of shock waves reflects unexpected and non-obvious results. Applicants therefore respectfully request withdrawal of the obviousness rejections under 35 U.S.C. §103.

Claims 38 and 49 stand rejected as being unpatentable as obvious over George in view of Ogden in view of Sanctis, as applied to claims 37 and 46 above, and in further view of Applicants' admission of record. For the foregoing reasons as to non-obviousness of all of the limitations of independent claims 34 (from which claim 38 depends) and 47 (from which claims 49 depends), withdrawal of the obviousness rejections under 35 U.S.C. §103 to dependent claims 38 and 49 is requested.

In view of the presented amendment and for at least the foregoing reasons, Applicants respectfully request that a timely Notice of Allowance be issued in this case. Applicants' Attorney also cordially invites the Examiner to contact the undersigned at the telephone number provided below if such will advance the prosecution of the instant application.

Applicant has included a petition and the requisite fee for a three-month extension of time under 37 C.F.R. §1.136. Such additional extension fee should also be charged to Deposit Account No. 50-0206, Order No. 69643.002200. Any overpayment can be credited to Deposit Account No. 50-0206, Order No. 69643.002200. If any additional fees or extensions are due in connection with the filing of this Response or the accompanying papers, or otherwise in the course of prosecution of this application, the same are authorized, and please charge the fees to Hunton & Williams Deposit Account No. 50-0206, Order No. 69643.002200.

Respectfully submitted,


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